

Bedside glucose testing systems

<i>Part 1 of 7</i>	Abbott Diabetes Care 1420 Harbor Bay Parkway Alameda, CA 94502 510-749-5400 www.abbottdiabetescare.com
Name of instrument/First year sold	Precision Xceed Pro Blood Glucose and Beta-Ketone Monitoring System/2007
Professional or home use	professional and home use
List price	—
Units sold in U.S./Outside U.S./In 2009	—
Part of series of similar or related models	yes
Dimensions (H x W x D)/Weight	19.7 cm (7.7 in) × 7.5 cm (2.96 in) × 5.33 cm (2.1 in)/256 g (9 oz)
Analytical method/Technology/Enzyme system used	glucose-specific GDH-NAD enzyme and low applied voltage to minimize interference; beta-hydroxybutyrate, the predominant blood ketone DKA
Price per disposable reagent system unit	—
No. of dispos. reag. system units per basic package	glucose: 100 strips; ketone: 50 strips
No. of times analyses performed using 1 reag. system unit	1
Dispos. units shelf life/Reag. unit storage requirements	15–18 months/4°–30°C
Digital readout size/Keypad input capability	3.06 mm (normal), 8.16 mm (results)/menu selection, numeric, alphabetic
How results are displayed	true values
Specimen types/Sampling techniques	whole blood/drop, capillary transfer, touchable strips
Minimum specimen volume required	glucose: 0.6 µL; ketone: 1.5 µL
Suitable for samples from well/Sick neonates	yes/yes
Time from sample intro. to result availability	glucose: 20 seconds; ketone: 10 seconds
Batteries used/No. used/Avg. life of one set	AA or NiMH rechargeable/2/—
Avg. expected life of device/Mean time between failures	—
Device warranty/Service options	1 year, lifetime replacement with reagent contract/24-hour replacement
Loaners provided	yes
User list or user group	yes, list available upon request
Toll-free No. for customer questions/Hours	877-529-7185/24 hours, 7 days
Training and certif. program/No. training days provided	yes/depends on number of operators
Avg. time for lab to complete maintenance	none
Special cleansing procedures	no
Internal QC recommended or required	as defined by facility or institutional policy
Between instrument CV (based on PT) at these levels:	
• <50 mg/dL	70.5 mg/dL, CV=5.0% (4,259 labs)
• 100–200 mg/dL	121.4 mg/dL, CV=4.9% (8,177 labs)
• >400 mg/dL	409.6 mg/dL, CV=4.8% (8,052 labs)
• Program name, year/Challenge No./Level of mean glucose challenge sample	CAP Whole Blood Glucose Survey, WBG-C, 2008/—
Accuracy/Compared to what reference method or device	capillary blood: $y=0.94x + 1.6$; $r=0.98$ /YSI
Precision/Compared to what reference method or device	blood samples: CV 3.0% to 3.6%/YSI
Linear range	glucose: 20–500 mg/dL; ketone: 0.0–8.0 mmol/L
Suggested dynamic, measurement range	glucose: 20–500 mg/dL; ketone: 0.0–8.0 mmol/L
Contraindications	per labeling
Known interferences/High-altitude interference	per labeling/no
Restrictions based on hematocrit	yes, glucose: 20–70%; ketone: 30–60%
Electronic, optical function checks	battery, bar-code scanner, database, and temperature checks performed during power-up of meter
Sample quantity checks	fill-trigger electrode on each test strip specifically designed to start the test when sufficient sample is detected
When auto lock or shutdown occurs	user ID failure, QC failure
User defines QC lockout intervals/Lockout can be circumvented	yes/no
Device supports bar-code scanning of	operator & patient identifiers, reagent lot numbers, comment codes, control and linearity lot Nos.
Method of analyst ID/ID required	bar-code or manual ID entry/analyst ID optional
Internal memory size/Max. No. patient results stored	1,000 control test results, 6,000 operators, 6,000 patient IDs, 2,500 patient test results, 18 glucose test strip lots, 20 proficiency test results, 20 glucose linearity test results (1 panel, 5 levels, 4 replicates per level)
Information transfer capability:	
• Meters connect to	PrecisionWeb data management system, which in turn connects to LIS/HIS
• How meters are connected to external system to upload results/No. installations	direct serial, modem dial-in, hospital network/—
• Info. contained in transmission to external system	device unique identifiers, operator and patient IDs, results, QC identifiers, strip lots, comment codes, test dates & times
Hardware/software for data mgmt. system	Enterprise multi-user Web-based system running on highly redundant Dell server
No. of different mgmt. reports system can produce	25
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs, patient list, QC lockout and upload lockout parameters
System connected (live installations) to which LISs/HISs:	
• using screen animation/screen scraping	Cerner, Misys, PerSe, Meditech, SoftLab, CPSI, Vista, CHCS, GE Medical, ADAC, HBOC Star, McKesson Horizon Lab, Siemens Novius Lab
• using standard HL7 interface	Cerner, Misys, PerSe, Meditech, SoftLab
• using proprietary protocol interface	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes/Sybase
Distinguishing features (provided by vendors)	TrueID: technology to identify patients by name, gender, date of birth, alphanumeric data entry; TrueMeasure: test-strip technology detects adequate sample and minimizes chemical interference; TrueAccess: notification and lock-out technology helps ensure compliance with procedures

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Bedside glucose testing systems

<i>Part 2 of 7</i>	Arkray Inc. 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com	Arkray Inc. 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com
Name of instrument/First year sold	Assure Platinum/2010	Assure Pro/2006
Professional or home use	professional use	professional use
List price	—	free with competitive trade out
Units sold in U.S./Outside U.S./In 2009	—/—/1	—
Part of series of similar or related models	yes	yes
Dimensions (H x W x D)/Weight	4.5 x 2.5 x 1.2/2.8 oz	4.1 x 2.4 x 1 in/2.5 oz without battery
Analytical method/Technology/Enzyme system used	glucose oxidase	glucose oxidase
Price per disposable reagent system unit	contact sales representative	contact sales representative
No. of dispos. reag. system units per basic package	50 or 100	50 or 100
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	18 months/room temperature	18 months/room temperature
Digital readout size/Keypad input capability	—/none	—
How results are displayed	true values	true values
Specimen types/Sampling techniques	whole blood/drop	whole blood/capillary transfer
Minimum specimen volume required	0.5 µL	0.5 µL
Suitable for samples from well/Sick neonates	no/no	no/no
Time from sample intro. to result availability	7 seconds	10 seconds
Batteries used/No. used/Avg. life of one set	AAA/2/5,000 tests with 4 tests per day	1.5 V alkaline AAA/2/up to 5,000 tests
Avg. expected life of device/Mean time between failures	—	—
Device warranty/Service options	5 years/—	5 years/—
Loaners provided	yes	yes
User list or user group	no	no
Toll-free No. for customer questions/Hours	800-818-8877/24 hours, 7 days	800-818-8877/24 hours, 7 days
Training and certif. program/No. training days provided	yes/1 on-site	yes/as needed
Avg. time for lab to complete maintenance	daily: <5 minutes	weekly: 5 minutes
Special cleansing procedures	no	no
Internal QC recommended or required	control solution testing	as specified by accreditation
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	—	—
• 100–200 mg/dL	—	—
• >400 mg/dL	—	—
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	—
Accuracy/Compared to what reference method or device	slope=1.00, y-intercept= -2.33, r=0.99/YSI model 2300	slope=0.94, y-intercept=0.63, r=0.99/YSI glucose analyzer
Precision/Compared to what reference method or device	For glucose results ≥75mg/dL, 100% within ±20%; 96% within ±15%; 79% within ±10%; and 53% within ± 5%. For glucose results <75 mg/dL, 100% within ± 15mg/dL; 100% within ± 10 mg/dL; 88% within ± 5 mg/dL	For glucose results ≥75mg/dL, 100% within ±20%; 99% within ±15%; 91% within ±10%; and 66% within ± 5%. For glucose results <75 mg/dL, 100% within ± 15mg/dL; 100% within ± 10 mg/dL; 92% within ± 5 mg/dL
Linear range	20–600 mg/dL	20–600 mg/dL
Suggested dynamic, measurement range	20–600 mg/dL	20–600 mg/dL
Contraindications	yes, see labeling	yes
Known interferences/High-altitude interference	yes/per labeling	per labeling/no, tested up to 10,000 feet
Restrictions based on hematocrit	yes, 30%–55%	yes, 30%–55%
Electronic, optical function checks	automatic	automatic, electronic
Sample quantity checks	—	—
When auto lock or shutdown occurs	—	—
User defines QC lockout intervals/Lockout can be circumvented	—	no/—
Device supports bar-code scanning of	no bar-code scanner	no bar-code scanner
Method of analyst ID/ID required	—	—
Internal memory size/Max. No. patient results stored	500/500 tests	250 tests with time & date stamp/250 test results
Information transfer capability:		
• Meters connect to	—	—
• How meters are connected to external system to upload results/No. installations	—	—
• Info. contained in transmission to external system	—	—
Hardware/software for data mgmt. system	—	—
No. of different mgmt. reports system can produce	—	—
Contents downloaded from DMS to meter	—	—
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	—	—
• using standard HL7 interface	—	—
• using proprietary protocol interface	—	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	—	no
Distinguishing features (provided by vendors)	auto coding, no need to manually code the meter; qcProGuard, a 24-hour control solution reminder; strip-release button, no need to touch used test strips	24-hour optional control solution reminder; top-of-meter strip insertion; strip-release button; backlight display; new strip launched late 2009

Bedside glucose testing systems

<i>Part 3 of 7</i>	Arkray Inc. 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com	HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630-2244 800-323-1034 www.hemocue.com
Name of instrument/First year sold	Assure 4/2007	Glucose 201 DM Analyzer/2005
Professional or home use	professional use	professional use
List price	free with competitive trade out	—
Units sold in U.S./Outside U.S./In 2009	—	—
Part of series of similar or related models	yes	yes
Dimensions (H x W x D)/Weight	3.9 x 2.3 x 1.0 in/2.5 oz without batteries	6.7 x 3.7 x 2 in/0.77 lb
Analytical method/Technology/Enzyme system used	glucose oxidase	absorbance photometry/glucose dehydrogenase
Price per disposable reagent system unit	contact sales representative	—
No. of dispos. reag. system units per basic package	50 or 100	25 in vial/box; 4 vials/boxes per package
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	18 months/room temperature	9 months from manufacture date/refrigeration
Digital readout size/Keypad input capability	—/none	varies from 8 to 28 points/menu selection, numeric, alphabetic
How results are displayed	true values	calculated values (plasma equivalent values [11%] measured whole blood value x 1.11)
Specimen types/Sampling techniques	whole blood/capillary transfer	whole blood (capillary, venous, arterial)/exact amount of blood drawn into cuvette by capillary force
Minimum specimen volume required	1.5 µL	5 µL
Suitable for samples from well/Sick neonates	no/no	yes/no (may require laboratory confirmation)
Time from sample intro. to result availability	10 seconds	40–240 seconds
Batteries used/No. used/Avg. life of one set	1.5 V alkaline AAA/2/3,000 tests	rechargeable lithium ion supplied by HemoCue/—/several years
Avg. expected life of device/Mean time between failures	—	7 years/>5 years
Device warranty/Service options	5 years/—	2 years, at no additional cost/replacement of defective analyzer
Loaners provided	yes	yes
User list or user group	no	no
Toll-free No. for customer questions/Hours	800-818-8877/24 hours, 7 days	800-323-1674, 6 AM–5 PM PST
Training and certif. program/No. training days provided	yes/as needed	yes/~1 hour per device purchased
Avg. time for lab to complete maintenance	weekly: 5 minutes	daily: ≤5 minutes
Special cleansing procedures	no	no
Internal QC recommended or required	as specified by accreditation	one level of controls prior to patient testing, each day of testing
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	—	not available
• 100–200 mg/dL	—	3.8
• >400 mg/dL	—	≥272 mg/dL=2.9
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	Equalis (Swedish PT program), 2003/2003–03; 2003–07/272 mg/dL; 120 mg/dL
Accuracy/Compared to what reference method or device	slope=1.010/r=0.993/ YSI glucose analyzer	±10% or ±6% mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS
Precision/Compared to what reference method or device	4.1%/—	within run CV 1.9% (108 mg/dL)/—
Linear range	30–550 mg/dL	0–444 mg/dL
Suggested dynamic, measurement range	30–550 mg/dL	0–444 mg/dL
Contraindications	no	no
Known interferences/High-altitude interference	per labeling/no (tested up to 7,000 feet)	grossly lipemic samples, methemoglobin, glucosamine/no
Restrictions based on hematocrit	yes, 30%–55%	no
Electronic, optical function checks	sumcheck functions for electronics and software, no optics	internal electronic self-test automatically checks that the instrument's optronic unit is working properly
Sample quantity checks	—	visual inspection
When auto lock or shutdown occurs	—	user ID failure if configured to require operator ID; QC failure if configured to require quality control; number of device errors
User defines QC lockout intervals/Lockout can be circumvented	no/—	yes/no (stat testing may be allowed; 1–100 tests after QC interval)
Device supports bar-code scanning of	no bar-code scanner	operator & patient identifiers, reagent lot Nos., comments, log entries, lab ID
Method of analyst ID/ID required	—	alphanumeric manual entry or bar-code scan entry/optional
Internal memory size/Max. No. patient results stored	50-test memory/50	4,000 patient tests/500 QC tests, 500 analyzer log entries/4,000
Information transfer capability:		
• Meters connect to	—	analyzer connects to 201 DM docking stations (data management system, which can further transmit data)
• How meters are connected to external system to upload results/No. installations	—	direct USB/hospital network
• Info. contained in transmission to external system	—	device unique identifiers, operator & patient IDs, results, QC identifiers, POCT-1A standard compliant, date/time, lab ID, flags
Hardware/software for data mgmt. system	—	PC/server/HemoCue 201 DM–DMS software
No. of different mgmt. reports system can produce	—	15 different templates, custom reports based on templates, multiple export formats
Contents downloaded from DMS to meter	—	cuvette lot No., valid control values, valid operator IDs, comments, analyzer log entries, analyzer configuration
System connected (live installations) to which LISs/HISs:	—	—
• using screen animation/screen scraping	—	—
• using standard HL7 interface	—	—
• using proprietary protocol interface	—	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	—	Telcor QML/Quick-Linc, Radiometer Radiance, Conworks POCcelerator
Distinguishing features (provided by vendors)	small sample size: 1.5 µL; fast test time: 10 seconds; large strip handle	POCT-1A compliant; indicated for diagnosis of diabetes mellitus; not hematocrit-dependent

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<i>Part 4 of 7</i>	HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630-2244 800-323-1034 www.hemocue.com	ITC 8 Olsen Ave. Edison, NJ 08820 800-631-5945 www.itcmed.com
Name of instrument/First year sold	Glucose 201 Analyzer/2002	IRMA TRUpoint (glucose module)/—
Professional or home use	professional use	professional use
List price	—	\$350
Units sold in U.S./Outside U.S./In 2009	—	—
Part of series of similar or related models	yes	no
Dimensions (H x W x D)/Weight	6.3 × 3.4 × 1.7 in/0.77 lb	5 × 9.5 × 13.5 in/6 lb (IRMA TRUpoint)
Analytical method/Technology/Enzyme system used	absorbance photometry/glucose dehydrogenase	glucose only: reflectance photometry, glucose oxidase
Price per disposable reagent system unit	—	—
No. of dispos. reag. system units per basic package	25 in vial/box; 4 vials/boxes per package	50 strips
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	9 months from manufacture date/refrigeration	strip: 18 months/room temperature
Digital readout size/Keypad input capability	0.5 in/none	4.5 x 2.5 in/menu selection, numeric, alphabetic
How results are displayed	plasma equivalent values	true values
Specimen types/Sampling techniques	whole blood, venous, capillary, or arterial/exact amount of blood is drawn into the cuvette by capillary force	whole blood/drop, capillary transfer, touchable strip
Minimum specimen volume required	5 µL	1 drop
Suitable for samples from well/Sick neonates	—	yes/yes
Time from sample intro. to result availability	40–240 seconds	<45 seconds
Batteries used/No. used/Avg. life of one set	AA/4/150 hours	rechargeable NiMH battery/1/3 years
Avg. expected life of device/Mean time between failures	7 years/>5 years	>5 years/<3% warranty return rate
Device warranty/Service options	2 years at no extra cost/—	1 year/extended warranty service available
Loaners provided	yes	24-hour replacement upon request
User list or user group	—	yes
Toll-free No. for customer questions/Hours	800-323-1674, 6 AM–5 PM PST	800-631-5945/24 hours, 7 days
Training and certif. program/No. training days provided	yes/as needed	yes/depends on No. of operators
Avg. time for lab to complete maintenance	daily: ≤5 minutes	clean glucose module as needed, 2 minutes
Special cleansing procedures	no	no
Internal QC recommended or required	system must be verified on testing days using commercially available controls	based on hospital-specific policy
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	not available	4.39%
• 100–200 mg/dL	3.8	3.44%
• >400 mg/dL	≥272 mg/dL=2.9	4.97%
• Program name, year/Challenge No./Level of mean glucose challenge sample	Equalis (Swedish PT program), 2003/2003-03; 2003-07/272 mg/dL; 120 mg/dL	data from 2000 AACC poster
Accuracy/Compared to what reference method or device	±10% or ±6 mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS	r >0.98/YSI
Precision/Compared to what reference method or device	within run CV 1.9% (108 mg/dL)/—	3.44–4.97 CV across runs/—
Linear range	0–444 mg/dL	0–500 mg/dL
Suggested dynamic, measurement range	0–444 mg/dL	0–500 mg/dL
Contraindications	no	excessive H₂O loss or dehydration
Known interferences/High-altitude interference	grossly lipemic samples, methemoglobin, glucosamine/no	sodium fluoride/no
Restrictions based on hematocrit	no	yes, <25% high results, >60% low results
Electronic, optical function checks	internal electronic self-test automatically checks that the instrument's optronic unit is working properly	optical self-zeroing; has LED to detect errors & internal check strip that is part of strip holder, automatically done with every test
Sample quantity checks	visual inspection	uses LED to determine sufficient quantity
When auto lock or shutdown occurs	—	user ID failure, QC failure, lockout if reagent expired or if control lot & reagent not entered
User defines QC lockout intervals/Lockout can be circumvented	no/no	yes/no
Device supports bar-code scanning of	no bar-code scanner	bar-code scanner available
Method of analyst ID/ID required	—	touchscreen/optional or required, QA user setup
Internal memory size/Max. No. patient results stored	—	4 MB RAM, 4 MB ROM, 256 KB nonvolatile/200 patient results
Information transfer capability:		
• Meters connect to	—	data management system, which connects to LIS/HIS; also directly to LIS/HIS
• How meters are connected to external system to upload results/No. installations	—	direct serial/—, modem dial-in/—, Ethernet/—
• Info. contained in transmission to external system	—	device unique identifiers, operator & patient IDs, results, QC identifiers, results dates & times, strip/material lots, up to 3 alphanumeric notes, result flags, reference range/QC limits, software revision, sample types
Hardware/software for data mgmt. system	—	nondedicated IBM compatible PC, Integrated Data Management System
No. of different mgmt. reports system can produce	—	6
Contents downloaded from DMS to meter	—	strip lot Nos., valid control values, valid operator IDs
System connected (live installations) to which LISs/HISs:	—	
• using screen animation/screen scraping	—	major vendors
• using standard HL7 interface	—	major vendors
• using proprietary protocol interface	—	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	—	yes, through laboratory data systems
Distinguishing features (provided by vendors)	CLIA-waived; indicated for diagnosis of diabetes mellitus; not hematocrit-dependent; lab verification of patient home meter	integrated workstation with IRMA TRUpoint (blood gas, electrolytes, BUN, creatinine, lactate, cartridge glucose test, Hct); 1 user interface, 1 in-service program, 1 data management system

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<p><i>Part 5 of 7</i></p>	<p>LifeScan Inc. Healthcare Professional Line 1000 Gibraltar Dr., Milpitas, CA 95035-6312 800-524-7226 www.lifescan.com</p>	<p>Medtronic MiniMed Inc. 18000 Devonshire St. Northridge, CA 91325 800-646-4633 www.minimed.com</p>
<p>Name of instrument/First year sold</p>	<p>SureStep Flexx/2000</p>	<p>iPro Continuous Glucose Monitor (CGM)/2008</p>
<p>Professional or home use List price Units sold in U.S./Outside U.S./In 2009 Part of series of similar or related models Dimensions (H x W x D)/Weight Analytical method/Technology/Enzyme system used Price per disposable reagent system unit</p>	<p>professional use \$1,200 with bar-code scanner/\$1,300 with bar-code scanner, meter unlock, and bar-code scan required features/\$850 without bar-code scanner >44,000/>4,000/>3,000 yes 6.34 × 3.55 × 1.63 in/12.5 oz (with bar-code scanner), 12.1 oz (without) reflectance photometry/glucose oxidase by contract, volume</p>	<p>professional use \$1,299 for iPro Professional Starter Kit, \$899 for iPro Recorder/Charger — yes (third-generation professional CGM system) .37 × 1.40 × 1.12 in/<5 grams glucose oxidase \$35 unit glucose sensor (disposable)</p>
<p>No. of dispos. reagent system units per basic package No. of times analyses performed using 1 reagent system unit Dispos. units shelf life/Reagent unit storage requirements</p>	<p>Two 25-strip vials (50 strips per box) 1 18 months unopened/<30°C (86°F); away from heat, direct sunlight</p>	<p>10 per box, 4 per box each sensor is indicated for 72-hour use 6 months/non-refrigeration 36°–80°F (2°–27°C)</p>
<p>Digital readout size/Keypad input capability How results are displayed Specimen types/Sampling techniques Minimum specimen volume required Suitable for samples from well/Sick neonates Time from sample intro. to result availability Batteries used/No. used/Avg. life of one set Avg. expected life of device/Mean time between failures Device warranty/Service options Loaners provided</p>	<p>18-point font (16 pixels high, 8 pixels wide)/menu select., numeric, alphabetic true values whole blood (capillary, venous, arterial, neonatal)/drop, capillary transfer, touchable strip, off-meter dosing 5 µL, maximum 30 µL yes/yes 15-second minimum AA/3/1,000 test minimum 5-year minimum/<10% warranty return rate 1 year/extended service agreements available 24-hour replacement with new device</p>	<p>no patient monitor interface/blinded glucose values, retrospective data data is downloaded from iPro Recorder to computer; CGM reports viewed through office computer or printed, or both continuous monitoring and sampling of interstitial fluid glucose levels — no/no (indicated for age 7+) retrospective analysis after disconnection rechargeable battery, iPro CGM charger, AAA/1/— 1 year/— 6 months for iPro Recorder/no warranty on disposables no</p>
<p>User list or user group Toll-free No. for customer questions/Hours Training and certif. program/No. training days provided Avg. time for lab to complete maintenance Special cleansing procedures</p>	<p>yes (contact SureStep Flexx product manager) 800-524-7226/24 hours, 7 days, multiple languages yes/as negotiated <1 minute no</p>	<p>no 800-646-4633/5am–5pm PST yes (training only)/~1 day none no</p>
<p>Internal QC recommended or required Between instrument CV (based on PT) at these levels: • <50 mg/dL • 100–200 mg/dL • >400 mg/dL • Program name, year/Challenge No./Level of mean glucose challenge sample</p>	<p>as defined by hospital policy 2.5% 2.9% 2.4% data from 2000 & 2001 AACC posters</p>	<p>none — 5% (40–400 mg/dL) in vitro — CGMS 1999, CGMS Gold 2003, iPro CGM 2008</p>
<p>Accuracy/Compared to what reference method or device Precision/Compared to what reference method or device Linear range Suggested dynamic, measurement range Contraindications Known interferences/High-altitude interference Restrictions based on hematocrit Electronic, optical function checks Sample quantity checks When auto lock or shutdown occurs User defines QC lockout intervals/Lockout can be circumvented Device supports bar-code scanning of Method of analyst ID/ID required Internal memory size/Max. No. patient results stored</p>	<p>r>0.98/YSI 3.44–4.97 CV across runs/— 0–500 mg/dL 0–500 mg/dL excessive water loss or dehydration sodium fluoride/no adults: 25%–60%; neonates: 25%–65% automatic electronic and optical checks with each test test strip color confirmation dot when adequate sample applied; meter error messages user ID failure, QC failure, failure to transfer data yes/yes, automatic meter unlock feature requires no user intervention operator & patient identifiers, reagent (strip) lot Nos., control solution lot Nos., meter serial Nos. unique alphanumeric ID/optional (defined by location) 256 KB/1,500 patient +QC tests, 50-test strip lots and 50 QC lots</p>	<p>coefficient of variation (CV) of 5%/fingerstick blood glucose measurements —/home glucose meters — 40–400 mg/dL no possibly MRI/no no test plug none none no/no no bar-code scanner at time of monitor download/optional up to 14 days continuous data/288 readings per day</p>
<p>Information transfer capability: • Meters connect to • How meters are connected to external system to upload results/ No. installations • Info. contained in transmission to external system</p>	<p>OneTouch DataLink data management system via wireless network, network and modem connectivity solutions. OneTouch DataLink can be interfaced with LIS/HIS OneTouch DataLink Connect connectivity solutions; wireless/network, modem connectivity/1,400 hospital sites, DataLink Interface >600 device unique identifiers, operator & patient IDs, results, QC identifiers, result flags, location/site</p>	<p>iPro Recorder and meters upload data to office computer iPro Recorder wirelessly transmits to ComLink, which connects via serial port or USB; meters connect via serial port or USB depending on meter sensor values, meter values and events (meals, insulin, exercise, and other)</p>
<p>Hardware/software for data mgmt. system No. of different mgmt. reports system can produce Contents downloaded from DMS to meter System connected (live installations) to which LISs/HISs: • using screen animation/screen scraping • using standard HL7 interface • using proprietary protocol interface Use 3rd-party interfacing tool/engine for LIS/HIS interfaces</p>	<p>hardware-independent/OneTouch DataLink data management system installation CD for Windows Vista & XP Pro; Telcor QML; OneTouch DataLink Web using Microsoft Windows Server 2003/2008 12 standard, unlimited customized reports, TGC advisor strip lot Nos., valid control values, valid operator IDs, critical value ranges, comment codes Cerner Citation, Cerner Classic, Cerner Premier, CHCS, HMS, McKesson ALG, McKesson Star Financial, McKesson Star Lab, Meditech Magic, RPMS, Sunquest, SoftLab Non-GUI, Vista Cerner Classic, Cerner Millennium, CPSI, Eclipsis, EPIC, Iatrics, McKesson Horizon Lab, McKesson Paragon, McKesson Horizon Clinicals, Mediserve, MediSolutions, Meditech Client Server, Meditech Magic, Meditech MagicHCA, Sunquest, Sunquest IGO, Omnetech, OpusLab, Siemens Invision, Siemens Novius Lab, Siemens LCR, SoftLab, TripleG, Vista, Repositories and Engines none yes, Telcor QML</p>	<p>ComLink for iPro CGM/Solutions software installed on the office computer 5 standard unlimited customized reports — does not interface LIS or HIS, a report from software—nontransferable no no no no</p>
<p>Distinguishing features (provided by vendors)</p>	<p>no risk of interference from maltose, xylose, or galactose; off-meter dosing helps with infection-control policies; configurable bar-code scanning options—allows truncation of leading and trailing characters; bar-code scan required feature; unique meter unlock; hardware-indepen. OneTouch DataLink data mgmt. software; wireless connectivity; compatible w/Telcor's QML; flexible database options; Citrix support</p>	<p>continuous glucose values every 5 minutes; limited patient education required with no additional device/receiver for patient to carry around; easy-to-read reports generated from office computer</p>

Bedside glucose testing systems

<i>Part 6 of 7</i>	Nova Biomedical Sales Department info@novabio.com 200 Prospect St. Waltham, MA 02454 781-894-0800 or 800-458-5813 www.novabiomedical.com	Roche Diagnostics Accu-Chek Customer Care Service Center 9115 Hague Rd., Indianapolis, IN 46256 800-440-3638 www.roche-diagnostics.us
Name of instrument/First year sold	StatStrip Glucose Monitoring System/2006	AccuData GTS, 1994; AccuData GTS Plus, 2000
Professional or home use	professional use	professional use
List price	call for pricing, includes bar-code reader, spare battery, quick reference guide	\$550
Units sold in U.S./Outside U.S./In 2009	—	40,000*/5,000/—
Part of series of similar or related models	yes	yes
Dimensions (H × W × D)/Weight	6.0 × 3.25 × 1.8 in/0.8 lb	11 × 8.75 × 4 in/5 lb
Analytical method/Technology/Enzyme system used	electrochemistry	biosensor—glucose dehydrogenase
Price per disposable reagent system unit	pricing based on volume	contingent on contract price
No. of dispos. reag. system units per basic package	50 strips per vial and 100 per box	50 strips per vial
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	24 months from date of manufacture/none	18 months, stable until expiration on vial/<90°F; do not freeze
Digital readout size/Keypad input capability	varies and is defined by the particular field/numeric, alphabetic	4 lines by 20 characters LCD/menu selection, numeric
How results are displayed	true values	true values
Specimen types/Sampling techniques	whole blood/drop (arterial, venous, capillary, neonatal)	whole blood/arterial, venous, capillary, neonate (including cord blood)
Minimum specimen volume required	1.2 µL	4 µL
Suitable for samples from well/Sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	6 seconds	26 seconds
Batteries used/No. used/Avg. life of one set	3.7 Li Polymer (rechargeable/replaceable)/1/24–36 months	3 V lithium/2/~700 tests
Avg. expected life of device/Mean time between failures	5+ years/—	5 years/10,000 tests
Device warranty/Service options	2 years (extended 5-year warranty at additional cost)/meter replacement	AccuData GTS Plus/GTS system will be free from defects in materials & workmanship through life of Accu-Chek Comfort Curve test strip contract; overnight replacement, according to warranty policy, is available 24/7 365 days per year replaced under warranty
Loaners provided	yes	
User list or user group	no	yes (contact local account manager)
Toll-free No. for customer questions/Hours	800-458-5813/24 hours, 7 days, all year	800-440-3638/24 hours, 365 days per year
Training and certif. program/No. training days provided	yes/defined during implementation planning	yes/site-specific according to No. of employees
Avg. time for lab to complete maintenance	no user maintenance	none
Special cleansing procedures	no	no
Internal QC recommended or required	CLIA requirements 2 levels per day	daily, 2 levels
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	—	53.8 mg/dL SD=4.1 (6,088 labs)
• 100–200 mg/dL	—	191.4 mg/dL CV=4.7% (3,096 labs)
• >400 mg/dL	—	228.5 mg/dL CV=4.6% (6,099 labs)
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	CAP, 2001/WBG-C/see above
Accuracy/Compared to what reference method or device	R2=0.9978, slope=1.0127–2.0975/YSI 2300	y=0.991 x + 8.4, r=0.980/glucose hexokinase-Hitachi
Precision/Compared to what reference method or device	within run (whole blood=1.9%–3.6%) & (day to day=3.4%–4.7%) linearity standards/—	controls: low SD=2.83 mg/dL, mid CV=3.08%, high CV=2.82%; blood: low SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/glucose hexokinase
Linear range	10–600 mg/dL	10–600 mg/dL
Suggested dynamic, measurement range	10–600 mg/dL	10–600 mg/dL
Contraindications	—	per labeling
Known interferences/High-altitude interference	none/no, operates at altitudes up to 15,000 feet	per labeling/none up to 10,150 feet
Restrictions based on hematocrit	none (no Hct interference)	yes, glucose <200 mg/dL, 20%–65%; glucose >200, 20%–55%
Electronic, optical function checks	electronic checks for out-of-range glucose results, dosing, out-of-range Hct results	meter cradle communication with Advantage meter, GTS with code key, battery voltage test, internal database memory check, internal configuration check
Sample quantity checks	RapidFill sampling electronically checks for correct strip dosing	built-in electronic strip check, visual confirmation of sample volume
When auto lock or shutdown occurs	options include user ID failure, QC failure, required docking for data transfer	user ID failure (valid op.), QC failure, patient ID length, incorrect code key, incorrect Advantage meter
User defines QC lockout intervals/Lockout can be circumvented	yes/no, not if configured	yes/yes (information management system identifies operators who violate hospital policy)
Device supports bar-code scanning of	operator & patient identifiers, reagent, lot No., QC lots	operator & patient identifiers, comment codes
Method of analyst ID/ID required	medical record ID No., medical billing ID No., Accession ID No./ID required	numeric input or bar-code wand scan/yes
Internal memory size/Max. No. patient results stored	1,000 patient samples, 200 QC samples, 4,000 operators/1,000 tests	1,000 total patient, control, linearity, proficiency tests/1,000
Information transfer capability:		
• Meters connect to	Instrument Manager (NovaNet or Laboratory Data Systems AegisPOC) to Data Manager (Telcor QML/Quick-Linc or AegisPOC) then to LIS if required	information management system, which in turn connects to LIS/HIS
• How meters are connected to external system to upload results/No. installations	hospital network/—; wireless tote/—	direct serial/—, modem dial-in/—, hospital network/—
• Info. contained in transmission to external system	device unique identifier, operator & patient IDs, results, QC identifiers	device unique identifiers, operator & patient IDs, results, QC identifiers, strip lot Nos., download location, comment codes, proficiency & linearity samples
Hardware/software for data mgmt. system	connects to Telcor QML and Laboratory Data Systems AegisPOC provided by Telcor and Laboratory Data Systems	MAS RALS-Plus, MAS RALS-Lite†, MAS RALS-Notebook†
No. of different mgmt. reports system can produce		varies by Data Manager (customer defined)
Contents downloaded from DMS to meter	strip lot numbers, valid control values, valid operator IDs, patient demographics, configuration files, physician IDs, diagnostic codes	strip & QC lot Nos., valid operator IDs, valid control values, linearity values
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	available through Telcor & Laboratory Data Systems	all major LIS vendors including Cerner, Misys, McKesson, Meditech, SoftLab, Siemens, SIA Molis, Opus, others**
• using standard HL7 interface	yes	—
• using proprietary protocol interface	no	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes, Telcor QML/Quick-Linc, Laboratory Data Systems AegisPOC	MAS
Distinguishing features (provided by vendors)	measures and eliminates interferences from hematocrit, oxygen, acetaminophen, ascorbic acid, uric acid, and other electrochemical substances; no interference from maltose, galactose, or xylose; no calibration codes required; results reported in 6 seconds using 1.2 µL of sample; unlimited manual test entry; 1-D and 2-D bar-code capability available	proven bi-directional network connection from AccuData GTS/GTS Plus to LIS/HIS; ADT data interface with RALS-Plus/DataCare POC; uses the Accu-Chek Comfort Curve test strip; universal sampling due to oxygen-independent chemistry, with reliable results at varying hematocrit levels

*combined AccuData GTS and AccuData GTS Plus sales

†Roche exclusive

**both scripted/HL7 are available

Bedside glucose testing systems

<i>Part 7 of 7</i>	<p>Roche Diagnostics Accu-Chek Customer Care Service Center 9115 Hague Rd., Indianapolis, IN 46256 800-440-3638 www.roche-diagnostics.us</p>	<p>YSI Life Sciences Jamie Lussier jlussier@ysi.com 1725 Brannum Lane, Yellow Springs, OH 45387 800 659-8895 www.ysilifesciences.com</p>
Name of instrument/First year sold	Accu-Chek Inform System/2001	YSI 2300 STAT Plus Glucose & Lactate Analyzer/1989
Professional or home use	professional use	professional use
List price	\$1,200	\$11,350
Units sold in U.S./Outside U.S./In 2009	67,000/10,000/—	—
Part of series of similar or related models	yes	yes
Dimensions (H x W x D)/Weight	1.4 x 3.8 x 7.6 in/12 oz	35.6 x 35.6 x 25.4 cm/25 lbs. (11.4 kg)
Analytical method/Technology/Enzyme system used	biosensor—glucose dehydrogenase	enzyme electrode, hydrogen peroxide, glucose oxidase
Price per disposable reagent system unit	contingent on contract price	\$15 per membrane sensor (cost per test: \$0.14 @ 2,000 patient samples)
No. of dispos. reag. system units per basic package	50 test strips	4 membranes per package
No. of times analyses performed using 1 reag. system unit	1	time based 3 weeks, 1000+ patient samples
Dispos. units shelf life/Reag. unit storage requirements	18 months, stable until expiration date on vial/room temperature less than 90°F, do not freeze	1 year/liquid reagents: room temp.; membrane sensor: 4°C refrigerated
Digital readout size/Keypad input capability	font size varies/menu selection, numeric, alphabetic	font hgt: 0.2 in., 2 x 40 alphanumeric LCD/menu selection, numeric
How results are displayed	true values	true and calculated values
Specimen types/Sampling techniques	whole blood/arterial, venous, capillary, neonate (including cord blood)	plasma, serum, whole blood/probe aspirated 25 µL
Minimum specimen volume required	4 µL	35–50 µL, dependent upon tube style
Suitable for samples from well/Sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	26 seconds	65 seconds
Batteries used/No. used/Avg. life of one set	3.7 V rechargeable lithium ion/1/testing in progress	AC line power/—/—
Avg. expected life of device/Mean time between failures	5 years/542,000 tests	10 years+/unknown
Device warranty/Service options	Accu-Chek Inform System will be free from defects in materials & workmanship through life of the Accu-Chek Comfort Curve test strip contract; overnight replacement, according to warranty policy, is available 24/7, 365 days per year	1 year/on all parts and labor/on-site service, dealer service centers, manufacturer service center in Ohio
Loaners provided	replaced under warranty	yes
User list or user group	yes (contact local account manager)	no (YSI 2300 is a reference blood instrument)
Toll-free No. for customer questions/Hours	800-440-3638/24 hours, 365 days per year	yes/8 AM-5 PM EST USA
Training and certif. program/No. training days provided	yes/site-specific according to No. of employees	yes/onsite: 1 day; vendor office: negotiable
Avg. time for lab to complete maintenance	none	daily: 15 min (calibration and check solution sample); weekly: 30 min (buffer solution change); monthly: 30 min (calibration solution and buffer solution change)
Special cleansing procedures	acceptable active ingredients: water, soap, 70% (or less) isopropyl alcohol, 1:10 dilution of sodium hydrochlorite	no
Internal QC recommended or required	daily, 2 levels of glucose control solutions	run a daily third-party control, such as a serum control
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	53.8 mg/dL SD=4.1 (6,088 labs)	2.5 mg/dL*
• 100–200 mg/dL	191.4 mg/dL CV=4.7% (3,096 labs)	2%*
• >400 mg/dL	228.5 mg/dL CV=4.6% (6,099 labs)	2%*
• Program name, year/Challenge No./Level of mean glucose challenge sample	CAP, 2001/WBG-C/see above	—
Accuracy/Compared to what reference method or device	$y=0.991x + 8.4$, $r=0.980$ /glucose hexokinase—Hitachi	YSI enzyme electrode technology commonly used whole blood glucose standard; YSI 2300 used as reference method for blood glucometer development and glucometer test strip QA
Precision/Compared to what reference method or device	controls: low SD=2.83 mg/dL, mid CV=3.08%, high CV=2.82%; blood: low SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/glucose hexokinase	hexokinase/UV spectrophotometric compared to plasma
Linear range	10–600 mg/dL	glucose: 0 to 900 mg/dL (9,000 mg/L, 50.0 mmol/L)
Suggested dynamic, measurement range	10–600 mg/dL	glucose: 0 to 900 mg/dL (9,000 mg/L, 50.0 mmol/L)
Contraindications	yes, per labeling	no
Known interferences/High-altitude interference	per labeling/none up to 10,150 ft	none that are biological in nature/no
Restrictions based on hematocrit	yes, glucose <200 mg/dL 20%–65%; glucose >200 mg/dL 20%–55%	no
Electronic, optical function checks	meter with code key, battery voltage test, internal database memory check, internal configuration check	— (sensor technology is amperometric, not optically based)
Sample quantity checks	built-in electronic strip check, visible verification of sample volume	—
When auto lock or shutdown occurs	user ID failure (valid op.), QC failure, download interval lockout, patient ID length, reagent editing, mandatory comments, incorrect/missing code key, time, and data editing	calibration instability, low reagent levels, various electromechanical checks related to moving parts
User defines QC lockout intervals/Lockout can be circumvented	yes/no (optional QC pass/fail feature)	—
Device supports bar-code scanning of	operator & patient identifiers, reagent lot Nos.	no bar-code scanner
Method of analyst ID/ID required	alphanumeric or bar-code scan/yes	numeric identifier optional/optional
Internal memory size/Max. No. patient results stored	4,000 results/4,000 tests	—/last 32 results stored in internal buffer accessible by serial port
Information transfer capability:		
• Meters connect to	information management system, which in turn connects to LIS/HIS	— (requires customized software for LIS/HIS interface)
• How meters are connected to external system to upload results/No. installations	direct serial/—, modem dial-in/—, hospital network/—	—
• Info. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, strip lot Nos., QC identifiers, proficiency & linearity samples, comments, meter location, download location	—
Hardware/software for data mgmt. system	MAS RALS-Plus, MAS RALS-Lite*, MAS RALS-Notebook†, and MAS RALS-Web	through custom software, patient ID and results may be retrieved
No. of different mgmt. reports system can produce	varies by Data Manager (customer defined)	—
Contents downloaded from DMS to meter		—
System connected (live installations) to which LISs/HISs:	QC & strip lot Nos., valid control values, valid operator & patient IDs, meter configuration, linearity lot Nos. & values, comments	—
• using screen animation/screen scraping	all major LIS vendors including Cerner, Meditech, Misys, CPSI, SoftLab, Siemens, McKesson, SIA Molis, Opus, others**	—
• using standard HL7 interface	yes	—
• using proprietary protocol interface	—	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	MAS	—
Distinguishing features (provided by vendors)	uses the Accu-Chek Comfort Curve test strip; universal sampling due to oxygen-independent chemistry, with reliable results at varying hematocrit levels; offers alphanumeric touchscreen, onboard bar-code ID, and MAS RALS-Plus connectivity, including ADT feed, which provides two patient identifiers for confirmation; extends the quality of blood glucose programs to six other point-of-care tests by allowing the entry and transfer of manual test information	commonly used reference method for glucometers; ideal for hospital diabetes evaluation testing, for example, clamp studies; accurate stat whole blood glucose 1-minute result
	†Roche exclusive **both scripted/HL7 are available depending on LIS version	*based on YSI proof of claims testing